

REMARKS

Claims 1-28 and 36-40 are currently pending in the application. Applicants affirm the election of claims 1-28 and 36-40 and withdraw claims 29-35 from further consideration pursuant to 37 CFR Section 1.142(b), being directed to a nonelected invention, without prejudice to the subject matter thereof. Applicants specifically reserve the right to file a divisional application at a later date to reintroduce these claims.

Section 102 Rejection

In paragraph 2 on page 2 of the Office Action, claims 1-3, 6-9, 21, 27, 36, and 38 are rejected under 35 U.S.C. §102 (e) as being anticipated by Atala (U.S. Patent No. 6,368,859). Applicants respectfully traverse the rejection.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. Furthermore, all of the elements must be arranged as in the claim. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984). Applicants respectfully submit that Atala does not teach every element of the invention set forth in independent claims 1 and 36, and therefore fails to anticipate claims 1 and 36.

Applicants respectfully submit that the Office Action does not make out a prima facie case of anticipation for the following reasons.

Atala does not teach each and every claim element. Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897, 1908 (Fed. Cir. 1990) (en banc), cert. Denied, 500 US 904 (1991).

Claim 1 recites, "A composite matrix comprising a first layer having at least about 5 dry weight percent flexibility modifying agent and a second layer having at least about 5 dry weight percent less flexibility modifying agent than the first layer, wherein at least one layer comprises a reconstituted composition."

Atala is directed to an artificial fascial sling for treating urinary incontinence. Atala does not disclose "a first layer having at least about 5 dry weight percent flexibility modifying agent," or a "second layer having at least about 5 dry weight percent less flexibility modifying agent than the first layer." Further, Atala does not disclose at least one layer including a reconstituted composition. The instant specification describes reconstituted compositions at page 16, lines 17-20: "Reconstituted compositions involve mixtures of synthetic or purified materials, possibly blended with fragmented natural materials, to form a non-natural material for incorporation into the composite. Thus the composites are distinguishable from native tissues that have layers."

Atala does not teach the identical invention in as complete detail as is contained in claim 1. "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP Section 2131. "Anticipation requires the presence in

a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Conell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)). Atala neither discloses, teaches nor suggests providing all of the following elements: (1) a *composite matrix* which (2) comprises a *first layer having at least about 5 dry weight percent flexibility modifying agent* and (3) a *second layer having at least about 5 dry weight percent less flexibility modifying agent than the first layer*, (4) *wherein at least one layer comprises a reconstituted composition*. Atala not only fails to teach each and every element of the invention of claim 1, but also fails to teach each and every element as arranged in the claim.

Atala also fails to teach all of the elements of independent claim 36. Atala neither teaches nor suggests all of the features of claim 36, fastening a first layer with a second layer, the first layer comprising at least about 25 weight percent collagen and the second layer comprising a flexibility modifying agent.

Dependent claims 2-3, 6-9, 21, and 27, and claim 38, which are dependent from independent claims 1 and 36, respectively, were also rejected under 35 U.S.C. §102(e) as being unpatentable over Atala. While Applicants do not acquiesce the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 1 and 36. These dependent claims include all of the limitations of the base claims and any intervening claims, and recite additional features which further patentably distinguish these claims from Atala. Therefore, dependent claims 2-3, 6-9, 21, 27, and 38 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 1-3, 6-9, 21, 27, 36, and 38 under 35 U.S.C. §102 (e) as being anticipated by Atala.

Section 103 Rejections

In paragraph 5 on page 3 of the Office Action, claims 1-28 and 36-40 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the teachings of Bell, et al. (U.S. Patent No. 5,891,558), Delmotte (U.S. Publication No. 2002/0131933 A1), Gregory (U.S. Patent No. 6,372,228), and Li, et al. (U.S. Patent No. 6,391,333) taken as a whole. Applicants respectfully traverse the rejection.

Applicants respectfully traverse the rejection since the Office Action fails to make out a *prima facie* case of obviousness. Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references. Second, there must be a reasonable expectation of success. Finally, the prior art combination of references must teach or suggest all the claim limitations. MPEP § 2142.

The cited references fail to disclose all the claim limitations and there would be no motivation to combine the references as proposed by the Examiner. Even if combined, the combination fails to teach or suggest all of the elements of the invention as claimed.

The fact that references can be combined or modified is not sufficient. That references could be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430, (Fed. Cir. 1990); MPEP Sec. 2143.01.

The cited combination fails to provide a suggestion to combine the references. Therefore, the suggestion to combine has come either from Applicants' own disclosure or impermissible hindsight. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP Sec. 2143. The Examiner must avoid hindsight. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990).

The cited combination, even if proper, fails to teach all of the elements of independent claim 1. The combination neither teaches nor suggests providing all of the following elements: (1) a *composite matrix* which (2) comprises a *first layer having at least about 5 dry weight percent flexibility modifying agent* and (3) a *second layer having at least about 5 dry weight percent less flexibility modifying agent than the first layer*, (4) *wherein at least one layer comprises a reconstituted composition*. The cited combination fails to teach each and every element of the invention of claim 1.

The cited combination also fails to teach all of the elements of independent claim 36. The combination neither teaches nor suggests all of the features of claim 36, fastening a first layer with a second layer, the first layer comprising at least about 25 weight percent collagen and the second layer comprising a flexibility modifying agent.

The claimed invention was not considered as a whole. In determining the differences between the prior art and the claims, the inquiry under section 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218

USPQ 698 (Fed. Cir. 1983); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985); MPEP Sec. 2141.02.

The Office Action must provide a specific reason to support an obviousness rejection. *Ex parte Humphreys*, 24 USPQ2d 1255 (BPAI 1992). However, the Office Action only stated "*Absent objective evidence to the contrary*, it would have been obvious to one of ordinary skill in the art to produce conventional materials (elastin and collagen) in conventional ways (multi-layered biopolymeric matrices) and include conventional additives (cells and growth factors)." The Office Action fails to provide a specific reason why it would have been obvious to combine the references. The phrase "absent objective evidence to the contrary, it would have been obvious....," reflects the impermissible hindsight reconstruction employed.

Absent a reference or references describing the absent elements, it also appears the Examiner is using personal knowledge, so the Examiner is respectfully requested to submit an affidavit as required by 37 CFR Sec. 1.104(d)(2). Applicants reserve the right to present further arguments in support of patentability of the invention as claimed over the cited combination.

In view of the foregoing, the Office Action has not made a *prima facie* case for obviousness. Withdrawal of the stated rejection is respectfully requested.

Dependent claims 2-28 and 37-40, which are dependent from independent claims 1 and 36, respectively, were also rejected under 35 U.S.C. §103(a) as being unpatentable over Bell, et al., Delmotte, Gregory and Li, et al. While Applicants do not acquiesce the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 1

and 36. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further patentably distinguish these claims from the cited references. If an independent claim is nonobvious under 35 USC 103, then any claim depending therefrom is nonobvious. MPEP Sec. 2143.03. Therefore, dependent claims 2-28 and 37-40 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 1-28 and 36-40 under 35 U.S.C. § 103(a) as being unpatentable over the teachings of Bell, et al.; Delmotte; Gregory; and Li, et al.

In view of the reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

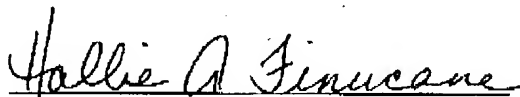
If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at (952) 253-4134.

Respectfully submitted,

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